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PATENT
Attorney Docket No.: 101.0083-00000
Customer No. 22882

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	Confirmation No.: 4911
Gary K. Michelson, M.D.	)	
Serial No.: 09/991,247	)	Group Art Unit: 3738
Filed: November 15, 2001	)	Examiner: P. Prebilic
For: RATCHETED BONE DOWEL	)	

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Commissioner for Patents
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Dear Sir:

Further to the Notice of Appeal dated July 30, 2004, transmitted herewith is an Appeal Brief (in triplicate) in the above-identified application.

- ☐ No additional fee is required.
- ☐ Applicant hereby requests a *** -month extension of time to respond to the above office action.
- ☒ A check in the amount of $330.00 to cover the Appeal Brief fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1066. **A copy of this sheet is enclosed.**
  - ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
  - ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

08/09/2004 JADD01 00000003 09991247
01 FC:1402 330.00 OP

Date: August 5, 2004

By: _____
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Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF

Gary K. Michelson, M.D., the inventor in the above-identified application, submits the following Brief in support of this appeal to the Board of the Examiner's rejection of claims 1-3 and 5-88 under U.S.C. § 103(a) as set forth in the Final Action dated January 30, 2004 and the Advisory Action dated May 14, 2004.

Real Party in Interest

The real party in interest is Gary Karlin Michelson, M.D. (hereinafter, the "Appellant").

Related Appeals and Interferences

There are no appeals or interferences pending which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claim 4 is cancelled.

Claims 1-3 and 5-88 are rejected and are on appeal.

In the Final Action, claims 1-3, 5-16, 18, 23-49, 55-78, and 84-88 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,860,973 to Michelson ("Michelson '973") in view of U.S. Patent No. 6,294,187 to Boyce et al. ("Boyce '187");

Claims 17, 50, and 79 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Michelson '973 and Boyce '187 in view of U.S. Patent No. 5,899,939 to Boyce et al. ("Boyce '939"); and

Claims 19-22, 51-54, and 80-83 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Michelson '973 and Boyce '187 in view of U.S. Patent No. 5,484,437 to Michelson ("Michelson '437").

Status of Amendments

In reply to the Final Action, Appellant amended claims 25-28, 56-59, and 85-88 in an Amendment After Final dated April 21, 2004. In the Advisory Action, the Examiner indicated that Appellant's Amendment After Final had overcome the rejections under 35 U.S.C. § 112, first and second paragraphs and would be entered for purposes of appeal. The Examiner further indicated that the amendment did not place the application in condition for allowance because "the Examiner does not believe that impermissible hindsight was used in the Section 103 rejections to arrive at the claimed invention because the secondary reference gives motivation for the combination." (Advisory Action, page 2, lines 3-5).

Summary of Invention

The implants claimed by Appellant are manufactured from a composite of cortical bone particles and at least one bioresorbable material, the cortical bone particles and the at least one bioresorbable material being combined to form a machinable material from which the implant is manufactured. (See page 10, lines 10-15). Various embodiments of the implant claimed by Appellant are summarized below.

Independent claim 1 is directed to a system including an interbody spinal implant (100) for insertion at least in part into an implantation space formed across a disc space

between adjacent vertebral bodies (V) of a human spine and into at least a portion of the endplates of the vertebral bodies. (Specification, page 10, lines 15-21; and Figs. 4-6). The implant has a body having a leading end for insertion first into the disc space and a trailing end (114) opposite the leading end; opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies; and opposite sides between the leading and trailing ends and between the upper and lower surfaces. (See Figs. 4-6). The upper and lower surfaces are arcuate in a direction from one of the opposite sides to another of the opposite sides. (Specification, page 10, line 17; and Figs. 4-6). A plurality of forward-facing projections (108) extend from the upper and lower surfaces for engaging the adjacent vertebral bodies. At least one of the projections has a leading face (112) and a rearward portion (110), the leading face and the rearward portion each having a length and a slope. The length of the leading face is longer than the length of the rearward portion. The slope of the rearward portion is steeper than the slope of the leading face. (Specification, page 10, line 23 through page 12, line 9; and Figs. 4 and 5). An opening (104) passes through the upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through the implant. (Specification, page 12, line 20 through page 13, line 5; and Fig. 4).

Independent claim 29 is directed to a system including an interbody spinal implant (400) for insertion at least in part into an implantation space formed across a disc space between adjacent vertebral bodies (V) of a human spine and into at least a portion of the endplates of the vertebral bodies. The implant has a body having a leading end for insertion first into the disc space, a trailing end (414) opposite the leading end, and a mid-longitudinal axis through the leading and trailing ends. The implant has a width transverse to the mid-longitudinal axis and a height transverse to both the width and the mid-longitudinal axis. The implant has a maximum width that is less than a maximum height. (Specification, page 15, line 17 through page 16, line 16; and Figs. 15-18). The implant has opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies and opposite sides

between the leading and trailing ends and between the upper and lower surfaces. An opening passes through the upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through the implant.

Independent claim 60 is directed to a system including an interbody spinal implant (200) for insertion at least in part into an implantation space formed across a disc space between adjacent vertebral bodies (V) of a human spine and into at least a portion of the endplates of the vertebral bodies. The implant has a body having a leading end for insertion first into the disc space, a trailing end (214) opposite the leading end, and a length therebetween. The implant has opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies and opposite sides (218a, 218b) between the leading and trailing ends and between the upper and lower surfaces. The opposite sides (218a, 218b) are at least in part smooth along a substantial portion of the length of the opposite sides. (Specification, page 14, lines 6-14; and Figs. 7-9A). The upper and lower surfaces are at least in part arcuate from one of the opposite sides to the another of the opposite sides. A plurality of projections (208) extend from the upper and lower surfaces for engaging the adjacent vertebral bodies to maintain the implant within the implantation space. An opening (206) passes through the upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through the implant.

Issues

1. Whether claims 1-3, 5-16, 18, 23-49, 55-78, and 84-88 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,860,973 to Michelson ("Michelson '973") in view of U.S. Patent No. 6,294,187 to Boyce et al. ("Boyce '187");

2. Whether claims 17, 50, and 79 are patentable under 35 U.S.C. § 103(a) over Michelson '973 and Boyce '187 in view of U.S. Patent No. 5,899,939 to Boyce et al.; and

3. Whether claims 19-22, 51-54, and 80-83 are patentable under 35 U.S.C. § 103(a) over Michelson '973 and Boyce '187 in view of U.S. Patent No. 5,484,437 to Michelson.

Grouping of Claims

The claims stand or fall together.

Argument

The Appellant submits the following arguments for consideration by the Board of Patent Appeals and Interferences:

(I) There is no motivation to combine the disclosures of Michelson '973 with Boyce '187.

In the Final Action, the Examiner states that Michelson '973 discloses an implant having a body (400) with upper (402) and lower (404) portions, side (406) portions, projections or ratchetings (220, 420), and openings as claimed. The Examiner further states that Michelson '973 lacks a composite of cortical bone and bioresorbable material as claimed. The Examiner contends that "it would have been considered prima fascia [sic] obvious to an ordinary artisan to make the Michelson implant out of the cortical bone/bioresorbable material composite of Boyce for the same reasons that Boyce does the same; see column 1, line 56 to column 2, line 4 of Boyce." (Final Office Action, page 4, first paragraph).

In the Advisory Action, the Examiner states that the "Examiner does not believe that impermissible hindsight was used in the Section 103 rejections to arrive at the claimed invention because the secondary reference gives motivation for the combination." (Advisory Action, page 2, lines 3-5).

Appellant submits that column 1, line 56 to column 2, line 4 of Boyce '187 states:

> "Many structural allografts are never fully incorporated by remodeling and replacement with host tissue due, in part, to the difficulty with which the host's blood supply may penetrate cortical bone, and partly to the poor osteoinductivity of nondemineralized bone. To the extent that the implant is incorporated and replaced by living host bone tissue, the body can then recognize and repair damage, thus eliminating failure by

fatigue. In applications where the mechanical load-bearing requirements of the graft are challenging, lack of replacement by host bone tissue may compromise the graft by subjecting it to repeated loading and cumulative unrepaired damage (mechanical fatigue) within the implant material. Thus, it is highly desirable that the graft have the capacity to support load initially, and be capable of gradually transferring this load to the host bone tissue as it remodels the implant."

(Boyce '187, col. 1, line 56 to col. 2, line 4).

Appellant respectfully submits that the foregoing passage of Boyce '187 cited by the Examiner to support his obviousness rejection does not provide the requisite motivation to combine Michelson '973 with Boyce '187. The passage relied upon by the Examiner identifies problems associated with bone grafts and not implants made of a material other than bone, such as the implants in Michelson '973 made of a material other than bone. In particular, Boyce '187 attempts to solve the problem of structural fatigue associated with bone grafts in certain applications.

Boyce '187 teaches how to make bone grafts stronger to increase their load bearing capacity. Boyce '187 teaches that instead of utilizing bone grafts obtained from shaped or cut bone segments, that instead bone is processed into a bone composite and formed under pressure into a desired shape. The composite material is stronger than the bone grafts from shaped or cut bone segments.

In contrast, Michelson '973 teaches that implants having a shape similar to Appellant's invention as claimed in independent claims 1, 29, and 60 are made of a material other than and stronger than bone. There would be no need to make these implants of Michelson '973 stronger as they did not suffer the load bearing problems that Boyce '187 was trying to solve. Moreover, these implants of Michelson '973 are already stronger than either bone grafts or the bone composite of Boyce '187. Boyce '187 does not mention any application of the principles of his invention applying to implants not made of bone. It is respectfully submitted that the Examiner's contention

that it would have been obvious to modify Michelson '973 "for the same reasons that Boyce does the same" is misplaced.

Appellant submits that one of ordinary skill in the art would not look to the teachings of Boyce '187 when presented with the teachings of Michelson '973 because Boyce '187 fails to supply any motivation for modifying implants not made of bone such as those taught by Michelson '973. Nowhere does Boyce '187 suggest modifying implants not made of bone to be manufactured from a composite of cortical bone particles and at least one bioresorbable material. Accordingly, Appellant submits that the requisite motivation needed to support the combination of Michelson '973 with Boyce '187 does not exist and that the rejections under 35 U.S.C. § 103(a) cannot be maintained.

(II) The Examiner is using impermissible hindsight in order to support the combination of Michelson '973 and Boyce '187.

Appellant respectfully submits that the Examiner is applying impermissible hindsight gleaned from Appellant's disclosure to support the combination of Michelson '973 and Boyce '187. In view of the arguments in Section (I) above, Appellant further submits that the teachings of Michelson '973 and Boyce '187 are mutually exclusive and that one of ordinary skill in the art would not look to combine the teachings of Michelson '973 and Boyce '187 without the benefit of Appellant's teachings in the disclosure of the present application. Accordingly, Appellant submits that the combination of Michelson '973 and Boyce '187 is untenable and cannot be maintained.

Accordingly, Appellant submits that independent claims 1, 29, and 60 are patentable over the art of record and that dependent claims 2, 3, 5-28, 30-59, and 61-88 dependent from one of independent claims 1, 29, and 60, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. § 1.16 or 1.17 which are not enclosed herewith, including

any fees required for an extension of time under 37 C.F.R. §1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: August 5, 2004

By: _____
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APPENDIX

1. A system including an interbody spinal implant for insertion at least in part into an implantation space formed across a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, said implant comprising:

a body having a leading end for insertion first into the disc space and a trailing end opposite said leading end;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies;

opposite sides between said leading and trailing ends and between said upper and lower surfaces, said upper and lower surfaces being arcuate in a direction from one of said opposite sides to another of said opposite sides;

a plurality of forward-facing projections extending from said upper and lower surfaces for engaging the adjacent vertebral bodies, at least one of said projections having a leading face and a rearward portion, said leading face and said rearward portion each having a length and a slope, the length of said leading face being longer than the length of said rearward portion, the slope of said rearward portion being steeper than the slope of said leading face;

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant; and

said implant being manufactured from a composite of cortical bone particles and at least one bioresorbable material, said cortical bone particles and said at least one bioresorbable material being combined to form a machinable material from which said implant is manufactured.

2. The system of claim 1, wherein said composite includes cortical bone fibers.

3. The system of claim 1, wherein said composite includes cortical bone filaments.

Claim 4 (cancelled).

5. The system of claim 1, wherein said bioresorbable material includes plastics.
6. The system of claim 1, wherein said bioresorbable material includes ceramic.
7. The system of claim 1, wherein said bioresorbable material includes composite plastics.
8. The system of claim 1, wherein at least one of said projections has a height as measured from the root diameter of said implant that is in the range of 0.25 mm to 1.5 mm.
9. The system of claim 1, wherein each of said projections comprises at least one of a ridge and a ratchet.
10. The system of claim 1, wherein said upper and lower surfaces are porous.
11. The system of claim 1, wherein said upper and lower surfaces include a bone ingrowth surface.
12. The system of claim 1, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.
13. The system of claim 1, wherein at least a portion of said leading end is tapered for facilitating insertion of said implant between the two adjacent vertebral bodies.
14. The system of claim 1, in combination with a fusion promoting material other than bone.
15. The system of claim 1, further in combination with bone morphogenetic protein.
16. The system of claim 1, further in combination with genetic material coding for production of bone.
17. The system of claim 1, further in combination with a chemical substance to inhibit scar formation.
18. The system of claim 1, in combination with at least one of hydroxyapatite and hydroxyapatite tricalcium phosphate.
19. The system of claim 1, in combination with a hollow tube configured to guide the insertion of said implant into the spine.
20. The system of claim 19, further in combination with a bone removal device configured for passage through said hollow tube.

21. The system of claim 20, wherein said bone removal device is one of a drill and a mill.

22. The system of claim 1, in combination with a driver instrument for inserting said implant into the spine.

23. The system of claim 1, wherein said opening is generally oval-shaped.

24. The system of claim 1, wherein said implant includes a plurality of openings passing though said upper and lower surfaces for permitting bone growth from adjacent vertebral body to adjacent vertebral body through said implant.

25. The system of claim 1, wherein said trailing end includes an opening for engagement with a driver instrument.

26. The system of claim 25, wherein said opening is threaded.

27. The system of claim 26, further comprising a second opening, said second opening being adapted to receive a peg.

28. The system of claim 1, wherein said trailing end includes up to four openings for engagement with the insertion instrument.

29. A system including an interbody spinal implant for insertion at least in part into an implantation space formed across a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, said implant comprising:

a body having a leading end for insertion first into the disc space, a trailing end opposite said leading end, a mid-longitudinal axis through said leading and trailing ends, a width transverse to the mid-longitudinal axis, and a height transverse to both the width and the mid-longitudinal axis, said implant having a maximum width that is less than a maximum height;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies;

opposite sides between said leading and trailing ends and between said upper and lower surfaces;

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant; and

said implant being manufactured from a composite of cortical bone particles and at least one bioresorbable material, said cortical bone particles and said at least one bioresorbable material being combined to form a machinable material from which said implant is manufactured.

30. The system of claim 29, wherein at least one of said opposite sides is at least in part arcuate.

31. The system of claim 29, wherein at least one of said opposite sides is at least in part convex.

32. The system of claim 29, wherein at least one of said opposite sides is at least in part concave.

33. The system of claim 29, wherein at least one of said opposite sides is at least in part flat.

34. The system of claim 29, wherein said upper and lower surfaces have a plurality of surface projections for engaging the adjacent vertebral bodies to maintain said implant within the implantation space.

35. The system of claim 34, wherein said surface projections comprise at least one of ridges, ratcheting, splines, and knurling.

36. The system of claim 34, wherein said surface projections are forward-facing to facilitate insertion into the implantation space and to prevent expulsion of said implant in a direction opposite to the direction of insertion of said implant into the implantation space.

37. The system of claim 29, wherein said composite includes cortical bone fibers.

38. The system of claim 29, wherein said composite includes cortical bone filaments.

39. The system of claim 29, wherein said bioresorbable material includes plastics.

40. The system of claim 29, wherein said bioresorbable material includes ceramic.

41. The system of claim 29, wherein said bioresorbable material includes composite plastics.

42. The system of claim 29, wherein said upper and lower surfaces are at least in part arcuate.

43. The system of claim 29, wherein said upper and lower surfaces are porous.

44. The system of claim 29, wherein said upper and lower surfaces include a bone ingrowth surface.

45. The system of claim 29, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.

46. The system of claim 29, wherein at least a portion of said leading end is tapered for facilitating insertion of said implant between the two adjacent vertebral bodies.

47. The system of claim 29, in combination with a fusion promoting material other than bone.

48. The system of claim 29, in combination with a fusion promoting substance.

49. The system of claim 48, wherein said fusion promoting material is at least one of bone, bone morphogenetic protein, genetic material coding for production of bone, hydroxyapatite, and hydroxyapatite tricalcium phosphate.

50. The system of claim 29, further in combination with a chemical substance to inhibit scar formation.

51. The system of claim 29, in combination with a hollow tube configured to guide the insertion of said implant into the spine.

52. The system of claim 51, further in combination with a bone removal device configured for passage through said hollow tube.

53. The system of claim 52, wherein said bone removal device is one of a drill and a mill.

54. The system of claim 29, in combination with a driver instrument for inserting said implant into the spine.

55. The system of claim 29, wherein said implant includes a plurality of openings passing though said upper and lower surfaces for permitting bone growth from adjacent vertebral body to adjacent vertebral body through said implant.

56. The system of claim 29, wherein said trailing end includes an opening for engagement with a driver instrument.

57. The system of claim 56, wherein said opening is threaded.

58. The system of claim 57, further comprising a second opening, said second opening being adapted to receive a peg.

59. The system of claim 29, wherein said trailing end includes up to four openings for engagement with the insertion instrument.

60. A system including an interbody spinal implant for insertion at least in part into an implantation space formed across a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, said implant comprising:

a body having a leading end for insertion first into the disc space, a trailing end opposite said leading end, and a length therebetween;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies;

opposite sides between said leading and trailing ends and between said upper and lower surfaces, said opposite sides being at least in part smooth along a substantial portion of the length of said opposite sides, said upper and lower surfaces being at least in part arcuate from one of said opposite sides to the another of said opposite sides;

a plurality of projections extending from said upper and lower surfaces for engaging the adjacent vertebral bodies to maintain said implant within the implantation space;

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant; and

said implant being manufactured from a composite of cortical bone particles and at least one bioresorbable material, said cortical bone particles and said at least one bioresorbable material being combined to form a machinable material from which said implant is manufactured.

61. The system of claim 60, wherein at least one of said opposite sides is at least in part arcuate.

62. The system of claim 60, wherein at least one of said opposite sides is at least in part convex.

63. The system of claim 60, wherein at least one of said opposite sides is at least in part concave.

64. The system of claim 60, wherein at least one of said opposite sides is at least in part flat.

65. The system of claim 60, wherein said surface projections comprises at least one of ridges, ratcheting, splines, and knurling.

66. The system of claim 60, wherein said surface projections are forward-facing to facilitate insertion into the implantation space and to prevent expulsion of said implant in a direction opposite to the direction of insertion of said implant into the implantation space.

67. The system of claim 60, wherein said composite includes cortical bone fibers.

68. The system of claim 60, wherein said composite includes cortical bone filaments.

69. The system of claim 60, wherein said bioresorbable material includes plastics.

70. The system of claim 60, wherein said bioresorbable material includes ceramic.

71. The system of claim 60, wherein said bioresorbable material includes composite plastics.

72. The system of claim 60, wherein said upper and lower surfaces are porous.

73. The system of claim 60, wherein said upper and lower surfaces include a bone ingrowth surface.

74. The system of claim 60, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.

75. The system of claim 60, wherein at least a portion of said leading end is tapered for facilitating insertion of said implant between the two adjacent vertebral bodies.

76. The system of claim 60, in combination with a fusion promoting material other than bone.

77. The system of claim 60, in combination with a fusion promoting substance.

78. The system of claim 77, wherein said fusion promoting material is at least one of bone, bone morphogenetic protein, genetic material coding for production of bone, hydroxyapatite, and hydroxyapatite tricalcium phosphate.

79. The system of claim 60, further in combination with a chemical substance to inhibit scar formation.

80. The system of claim 60, in combination with a hollow tube configured to guide the insertion of said implant into the spine.

81. The system of claim 80, further in combination with a bone removal device configured for passage through said hollow tube.

82. The system of claim 81, wherein said bone removal device is one of a drill and a mill.

83. The system of claim 60, in combination with a driver instrument for inserting said implant into the spine.

84. The system of claim 60, wherein said implant includes a plurality of openings passing though said upper and lower surfaces for permitting bone growth from adjacent vertebral body to adjacent vertebral body through said implant.

85. The system of claim 60, wherein said trailing end includes an opening for engagement with a driver instrument.

86. The system of claim 85, wherein said opening is threaded.

87. The system of claim 86, further comprising a second opening, said second opening being adapted to receive a peg.

88. The system of claim 60, wherein said trailing end includes up to four openings for engagement with the insertion instrument.